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EXAMINER	
UNDERDAHL, THANE E	

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1651	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/677,857	COOPER ET AL.	
	Examiner	Art Unit	
	Thane Underdahl	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-57* is/are pending in the application.

4a) Of the above claim(s) *11,12 and 18-55* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,13-17,56 and 57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the Applicant's request for reply received 6/5/07. Claims 1-57 are pending. Claims 11, 12 and 18-55 are withdrawn. No claims are cancelled. Claim 1 has been amended. Claims 56 and 57 are new.

Response to Applicant's Arguments Concerning the Species Election

The Applicant traverses the Examiner's withdraw of claims 11 and 12 as being dependent from non-elected species. The Examiner reminds the Applicant that They elected a non-ionic surface stabilizer. The surface stabilizers in claims 11 and 12 are expressly stated as cationic. Therefore they do not fall within the elected species and are withdrawn. The Applicant is invited to revisit the requirement for Restriction/Election filed 9/6/06 for reasons why these species are distinct.

Furthermore, the examiner wishes to point out for the record that an election of species requirement is for search purposes only and does not necessarily narrow the scope of patentable claims, since all nonelected species are rejoined at the time of allowance. See 37 C.F.R. §1.146 and M.P.E.P. § 809.02(c) for a discussion of species election practice. In short, electing one species does not preclude consideration of the nonelected species later in the prosecution, *i.e.* at the time of allowance. The fact that all of the original claims were generic was the precise reason for the requirement for species election; in the interest of expedient processing of applications, the examiner concentrates on the patentability of the entire invention as it pertains to one species. Once the invention *per se* is claimed in an allowable manner, all disclosed species are rejoined to the claims.

Response to Applicant's Arguments— 35 U.S.C § 103

In the response submitted by the Applicant, the 35 U.S.C § 103 (a) rejection of claims 1-10 over Ramirez et al. were considered but not found persuasive.

The Applicant argues that the Examiner has failed to show that particle size of the BP is a result effect variable and a matter of routine optimization by failing to show that one of ordinary skill in the art would recognize this fact and indeed be able to produce a BP particle of less than 2000 nm as limited in claim 1 and further limited in several dependent claims. However the Examiner has included several applications published before the Applicant's filing date that that enable one of ordinary skill in the art to make Benzyl Peroxide crystals of extremely small size.

Tarasov (U.S. Patent # 4,401,835) teach a precipitation method that prepares benzoyl peroxide crystals 10 microns and below (Tarasov, see abstract). His method teach that the crystals have a particles size ranging up to 10 microns and that size may be controlled by the "concentration of benzoyl peroxide initially added to the dispersing solution and/or by careful selections of the solvents and mixtures" (Tarasov, col 2 lines 8-15).

Futhermore Bagchi et al. (U.S. Patent # 5,662,883) teach a precipitation method that is similar to Tarasov that forms particles to pharmaceutical agents that have an average diameter of 10 nM (Bagchi, see Abstract). Bagchi et al. uses a similar precipitation strategy to Trasov where the agent to be crystallized is dissolved in a solution and then a surface active agent such as anionic and non-ionic surfactants (Bagchi, col 13, lines 15-45 and Tarasov, see Abstract).

Self (U.S. Patent # 4,917, 816) teach a milling method that combines benzoyl peroxide particles and a defoamer (surface stabilizer) that have a combined size of less than 10 microns a majority of which have a size from about 2 to 5 microns (Self, Example 1).

The Examiner believes that the teachings of these three references enable one of ordinary skill in the art to optimize the size of a benzoyl peroxide crystal.

The Applicant continues to argue that "Ramirez fails to disclose, identify, or appreciate the relationship between the particles of benzoyl peroxide and the surface stabilizer" (Applicant's Response page 16, last paragraph). However this argument is not commensurate with the scope of the claims, which simply state a "at least one surface stabilizer associated with the surface of the benzoyl peroxide particle" (Applicant's Claim 1). It is clear from the previous office action that Ramirez et al. includes in a mixture BP with non-ionic surface stabilizers such as colloidal silicon dioxide. Since these are in a mixture, one of ordinary skill in the art would immediately recognized that some of the non-ionic surface stabilizers are in contact, thus associated with the BP, which meets the limitations as defined in claim 1.

The Applicant argues that "the Examiner has ignored the criticality of selecting a surface stabilizer of the invention" and provides the following quotation from the Office Action: "absent any express teaching of the criticality of the surface stabilizers, claims 1 and 3 are prima facie obvious . . . .". However the Examiner did not make this statement in the Office Action mailed on 2/23/07. It is believed that the Applicant misquoted the Examiner and meant to quote "absent any teaching of criticality by the

applicant concerning the particle size listed in claims 1 and 3 it would be *prima facie* obvious that one of ordinary skill in the art would recognize that the particle size in claims 1 and 3 is a result effective variable which is a matter of routine optimization" (Previous Office Action page 4). It is believed that the optimization of the BP crystal size has been sufficiently address. Any further argument stemming from this misquotation is moot until further clarification is given by the Applicant.

The Applicant completes their arguments by stating any further rejections based on Ramirez in view of Kanios et al. or in further view of Bartnik et al. should be withdrawn since neither reference provides a remedy to the deficiencies of Ramirez. However, as stated above the claims remain unpatentable over Ramirez and as such these rejections stand as well.

Therefore these rejections stand and are repeated below with modifications to include the new claims.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10 as well as new claims 56 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramirez et al. (U.S. Patent # 5,632,996, 1997).

These claims are drawn to a composition comprising particles of benzoyl peroxide (**BP**) or a salt thereof that is present in an amount from about 99.5% to about 0.001% by weight, wherein the particles have an average size of less than 2000 nm, and also contains a surface stabilizer is present in an amount of about 0.5% to 99.999% by weight. These particles can be in a crystalline phase, amorphous phase, a semi-crystalline phase, or a semi-amorphous phase. Claim 3 further limits claim 1 by requiring the BP particles be less than 1900 nm in size. Claim 4 limits the formulation of the composition in claim 1 to creams. The composition further comprises pharmaceutically acceptable excipients, carriers, or a combination thereof.

The surface stabilizer is selected from the group of non-ionic surface stabilizers. Claim 9 further limits that the composition of claim 1 comprises at least two surface stabilizers. Claim 10 provides a list to limit the surface stabilizers, some of which are ionic and non-ionic.

Ramirez et al. teach a composition of BP that ranges from 70% to 5% by weight and a surface stabilizer of alkylbenzoate (**AB**) that ranges in the composition form 95% to 30% by weight (col 3, lines 50-65, and col 2, lines 59-68). These BP compositions can be formulated into a lotion, cream or gel (lines 29-31) or a solid dosage form such as a soap. The cream compositions contain other non-ionic surface stabilizers such as AP as well as colloidal silicon dioxide (col 4, line 40). The cream also contains pharmaceutically acceptable excipients and carriers such as glycolic acid and petrolatum (petroleum jelly).

Ramirez et al. also teach that their amorphous powder of BP is an art-defined equivalent to BP crystals in a cosmetic composition (col 3, line 28-46). Therefore it would be obvious for one of ordinary skill in the art to substitute one crystal phase of BP for another in a cosmetic formulation (M.P.E.P. § 2144.06).

What Ramirez et al. does not teach is the specific particle size of the BP in their composition. However one of ordinary skill in the art would recognize particle size is a result effective variable. Indeed Ramirez addresses particle size as important in the formulation by teaching "It would be desirable to provide a BP compositions...which have a smooth texture appropriate for cosmetic products" (col 1, lines 53-59) and BP "crystalline powder is gritty" and discusses the importance to "prepare a paste having benzoyl peroxide crystals that are sufficiently fine to be of acceptable texture for preparing products for topical use" (col 1, lines 30-40). Therefore one of ordinary skill in the art would recognize the importance of crystal size in the texture of a BP composition, and that finer crystals are required to reduce the grittyness of the composition to make it acceptable for topical use. One of ordinary skill in the art would also recognize from the teachings of Ramirez et al. that particle size can be adjusted to a desired texture. Therefore absent any teaching of criticality by the applicant concerning the particle size listed in claims 1 and 3 it would be *prima facie* obvious that one of ordinary skill in the art would recognize that the particle size in claims 1 and 3 is a result effective variable which is a matter of routine optimization (M.P.E.P. § 2144.05 II).

Therefore the references listed above renders obvious claims 1-10 and new claims 56 and 57.

Claims 1-10 and 14-16, 56, 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramirez et al. (U.S. Patent # 5,632,996) as applied to claim 1-10 above, and further in view of Kanios et al. (U.S. Patent # 5,719,197, 1998).

Claims 1-10 and new claims 56 and 57 are summarized above. Claims 14-16 further limit the composition of claim 1 by requiring the composition to be a bioadhesive, additionally comprise one or more non-BP active agents selected from the group of nutraceuticals, retinoic acid, antibiotics, sulfur and salicylic acid.

As mentioned above Ramirez et al. renders obvious claims 1-10 above by teaching a BP composition with a several surface stabilizers that can be formulated into a cream for cleansing the skin (col 1, lines 10-13) which includes acne treatment (col 4, lines 55-60). However Ramirez et al. does not teach the components of claims 13-17. These are taught in the by Kanios et al. Kanios et al. teach that their composition for topical applications of pharmaceutical agents and bioadhesive carriers can be formulated into an anti-acne composition containing BP and the additional active agent retinoic acid.

Since the anti-acne compositions of Ramirez et al. and Kanios et al. share common components to treat a common goal it would be obvious for one of ordinary skill in the art to add the composition of Ramirez et al. to the invention of Kanios. The motivation and reasonable expectation of success is provided by Kanios et al. who

teach an anti-acne composition with similar components to Ramirez et al.. Therefore, the invention as a whole would have been prima facie obvious at the time of filing in view of the references listed above and as such claims 1-10 and 14-16, 56, 57 are not allowable.

Claim 1-10 and 13-17, 56, 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramirez et al. and Kanios et al. as applied to claims 1-10 and 14-16, 56 and 57 above, and further in view of Bartnick et al. (U.S. Patent # 5,399,353, 1995).

Claims 1-10 as well as 14-16 are summarized above. Claim 13 further limits the composition of claim 1 by requiring the surface stabilizer is lysozyme, polyvinylpyrrolidone (**PVP**), benzalkonium chloride (**BKC**). Claim 17 limits the antibiotic to clindamycin or erythromycin.

Claims 1-10 are rendered obvious by Ramirez et al. Claims 1-10 and 14-16 are rendered obvious by the combination of Ramirez et al. and Kanios et al. While Kanios et al. does teach the addition of antibiotics clindamycin and erythromycin as well as lysozyme and PVP to their composition the motivation to add these components to a skin cleansing composition is provided by Bartnick et al.

Bartnick et al. teach a composition to disinfect undamaged skin (col 7, lines 15-20). In this composition they include strong disinfectants such as BP, lactic acid as well as PVP and lysozyme (col 7 line 65 to col 8 line 2). Ramirez et al. already adds the disinfectants lactic acid and BP to their composition (col 4, lines 35-45) and M.P.E.P. § 2144.06 states

> "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art."

Therefore it is *prima facie* obvious to one of ordinary skill in the art to add more disinfectants to the composition of Ramirez et al. and Kanios et al. as motivated by Bartnick et al.

Bartnick et al. also teach the addition of antibiotics to a composition to cleanes skin (col 7, line 62). Bartnick et al. is silent on which antibiotic. However Kanios et al. teach that the antibiotics clindamycin and erythromycin can be added to their skin composition (col 16, lines 63-65). One of ordinary skill in the art would recognize that antibiotics would be useful in treating skin diseases cause by bacterial infections such as acne. It would therefore have been obvious for the person of ordinary skill in the art to add the antibiotics of Kanios to the combined composition of Ramirez et al. and Kanios et al. The motivation is provided by Bartnick et al. who teach the additional components of a skin cleansing composition and the reasonable expectation of success is provided by the formulations of Kanios et al. Therefore, the invention as a whole would have been prima facie obvious at the time of filing in view of the references listed above and as such claims 1-10 and 13-17, 56, 57 are not allowable.

In summary no claims, as written, are allowed for this application.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-9042. The examiner can normally be reached Monday through Thursday, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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